

TYLO EXTRA (ACETAMINOPHEN)- acetaminophen tablet, delayed release
America Medic & Science, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Tylo Extra 1000 mg

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Drug Facts

Active Ingredient

Acetaminophen 1000 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- backache
- minor pain of arthritis
- temporarily reduces fever
- the common cold
- toothache
- menstrual cramps
- muscular aches

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease

Ask your doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms appear
- redness or swelling is present

These could be signs of a serious condition

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

do not take more than directed (see overdose warning).

Adults and children 12 years and over:

- take 1 caplet every 6 to 8 hours
- Do not take more than 4 caplets of this product in 24 hours.

Children under 12 years:

- do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store between 20-25°C (68-77°F)
- see end panel for lot number and expiration date

Inactive ingredients

- Povidone, Pregelatinized Starch, Crosspovidone Stearic Acid, Titanium Dioxide, Carnauba Wax Hypromellose, Polyethylene Glycol.

Questions or comments?

call toll free 1-855-470-6722

Package Labeling:

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| TYLO EXTRA (ACETAMINOPHEN) | | | |
|--|----------------|---------------------------|-----------------|
| acetaminophen tablet, delayed release | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49638-112 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | | ACETAMINOPHEN | 1000 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| POVIDONE (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| STARCH, CORN (UNII: O8232NY35J) | |
| CROSPVIDONE (UNII: 2S7830E561) | |

Product Characteristics

| | | | |
|----------|---------|--------------|----------|
| Color | white | Score | no score |
| Shape | CAPSULE | Size | 8mm |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49638-112-30 | 1 in 1 CARTON | 01/17/2019 | |
| 1 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 01/17/2019 | |

Labeler - America Medic & Science, LLC (071065464)**Registrant** - America Medic & Science, LLC (071065464)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Elvi Pharma LLC. | | 078739246 | manufacture(49638-112) |

Revised: 8/2021

America Medic & Science,
LLC